

Food and Drug Administration, HHS

§ 886.3800

in subpart E of part 807 of this chapter subject to § 886.9.

[52 FR 33355, Sept. 2, 1987, as amended at 63 FR 59230, Nov. 3, 1998]

§ 886.3130 Ophthalmic conformer.

(a) *Identification.* An ophthalmic conformer is a device usually made of molded plastic intended to be inserted temporarily between the eyeball and eyelid to maintain space in the orbital cavity and prevent closure or adhesions during the healing process following surgery.]

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9.

[52 FR 33355, Sept. 2, 1987, as amended at 63 FR 59230, Nov. 3, 1998]

§ 886.3200 Artificial eye.

(a) *Identification.* An artificial eye is a device resembling the anterior portion of the eye, usually made of glass or plastic, intended to be inserted in a patient's eye socket anterior to an orbital implant, or the eviscerated eyeball, for cosmetic purposes. The device is not intended to be implanted.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9, if the device is made from the same materials, has the same chemical composition, and uses the same manufacturing processes as currently legally marketed devices.

[61 FR 1124, Jan. 16, 1996, as amended at 66 FR 38813, July 25, 2001]

§ 886.3300 Absorbable implant (scleral buckling method).

(a) *Identification.* An absorbable implant (scleral buckling method) is a device intended to be implanted on the sclera to aid retinal reattachment.

(b) *Classification.* Class II.

§ 886.3320 Eye sphere implant.

(a) *Identification.* An eye sphere implant is a device intended to be implanted in the eyeball to occupy space following the removal of the contents

of the eyeball with the sclera left intact.

(b) *Classification.* Class II.

§ 886.3340 Extraocular orbital implant.

(a) *Identification.* An extraocular orbital implant is a nonabsorbable device intended to be implanted during scleral surgery for buckling or building up the floor of the eye, usually in conjunction with retinal reattachment. Injectable substances are excluded.

(b) *Classification.* Class II.

§ 886.3400 Keratoprosthesis.

(a) *Identification.* A keratoprosthesis is a device intended to provide a transparent optical pathway through an opacified cornea, either intraoperatively or permanently, in an eye that is not a reasonable candidate for a corneal transplant.

(b) *Classification.* Class II. The special controls for this device are FDA's:

(1) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' "

(2) "510(k) Sterility Review Guidance of 2/12/90 (K90-1)," and

(3) "Guidance on 510(k) Submissions for Keratoprostheses."

[65 FR 17147, Mar. 31, 2000]

§ 886.3600 Intraocular lens.

(a) *Identification.* An intraocular lens is a device made of materials such as glass or plastic intended to be implanted to replace the natural lens of an eye.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.3800 Scleral shell.

(a) *Identification.* A scleral shell is a device made of glass or plastic that is intended to be inserted for short time periods over the cornea and proximal-cornea sclera for cosmetic or reconstructive purposes. An artificial eye is usually painted on the device. The device is not intended to be implanted.

(b) *Classification.* Class II (special controls). The device is exempt from